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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,402

Applicant(s)

JIMENEZ ET AL

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 26-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25, drawn to an implantable medical device with a recharging coil, classified in class 607, subclass 61.
 - II. Claim 26, drawn to recharging coil for an implantable device, classified in class 607, subclass 57.
 - III. Claims 30-37, drawn to method of enhancing electromagnetic coupling of an implantable recharging coil, classified in class 607, subclass 59.
 - IV. Claims 38-45, drawn to method for reducing temperature rise during recharging of an implantable medical device external to recharging coil, classified in class 607, subclass 62.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a secondary charging coil having at least two leads coupleable to an implantable medical device. The subcombination has separate utility such as not requiring a

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rechargeable power source carried in the housing and coupled to the electronics, but rather rechargeable source outside the housing.

3. Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus not requiring a rechargeable power source, but for directly recharging the electronics.

4. Inventions IV and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as not requiring reducing temperature rise during recharging, but rather monitoring the temperature change.

5. Inventions III and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus not requiring a secondary recharging coil having at least two leads

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coupleable to an implantable medical device, but rather just having one lead coupleable to an implantable device.

6. Inventions IV and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another materially different process such as not requiring reducing temperature rise during recharging, but rather monitoring the temperature change.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with John Albrecht on November 19, 2002 a provisional election was made with traverse to prosecute the invention Group I, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Drawings

10. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 32, 82 and 84. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claims 1 and 23, "with" is vague because it is unclear if this is a positive recitation of the coil and "a proximal face" is vague since it is unclear what direction "proximal" is. It is suggested to use "external face". "An electrical feedthrough" makes the claim incomplete since there is no connection of the feedthrough to any other element. "A distal side" is vague since there is no set direction in the system and "the receiving recharging coil" lacks antecedent basis.

Referring to claim 2, "a primary recharging coil" is inferentially included and has not been positively recited. It is unclear if applicant is claiming this coil.

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Referring to claim 3, "is improved" is vague since it is unknown what element is doing the "improving".

Claims 4, 5, 24 and 25 are vague because applicant must state what element is doing the "improving". Also, in claim 5 "flux lines" is inferentially included and it is unclear what element is providing flux lines.

Claims 6-8 are vague because it is unknown what element is "reducing eddy currents and temperature". Also, in claims 6 and 7 "reduced eddy currents" and "during recharging" are both inferentially included and need to be positively recited. Also, in claim "wherein the temperature rise of the medical device during recharging is less than two degrees Celsius" is vague since it is unknown how much power is being generated in the coil, in order to reduce the temperature by two degrees.

Claim 9 is vague since it is unclear which claim it is depending on. The claim could not be further examined and also "high" is vague because it is a relative term.

Referring to claim 12, "eddy current flow" is inferentially included and needs to be positively recited.

Referring to claim 14, "first and second magnetic shield" are both inferentially included and need to be positively recited. Also, "a first magnetic shield" is vague. Is this the same shield used in claim 1.

Referring to claim 15, "a second magnetic shield" should be "said second magnetic shield" and "a third magnetic shield" is inferentially included and needs to be positively recited.

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Referring to claim 16, "a second insulator" is inferentially included and needs to be positively recited.

Referring to claim 17, "receiving recharging coil" lacks antecedent basis.

Referring to claim 18, "away" is vague because it is a relative term.

Claim Rejections - 35 USC § 102/103

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-8, 10, 11, 13, 14 and 17-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kelly et al. U.S. Patent No. 4,041,955.

Referring to claim 1, Kelly discloses an implantable medical device comprising:

- Electronics carried in the housing and configured to perform a medical therapy
- A rechargeable power source carried in the housing and coupled to the electronics (Fig 3)
- A secondary recharging coil coupled to the electronics and rechargeable power source (21)
- A magnetic shield placed on the distal side of the receiving coil to improve recharging efficiency (column 5, lines 22-26)

It is inherent that the housing has an electrical feedthrough since it has leads extending through the housing. In the alternative Kelly discloses the claimed invention except for an electric feedthrough. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention as taught by Kelly, with an electrical feedthrough since it is well known in the art that implantable devices have electrical feedthroughs for providing energy.

Referring to claim 18, wherein the secondary recharging coil is an external secondary charging coil located away from the housing (Fig 2).

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Referring to claim 19, wherein the recharging coil is located in the housing interior cavity (Fig 3).

17. Claims 1-8, 10, 11, 13, 14 and 17-25 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zarinetchi et al. U.S. Patent No. 6,324,431.

Referring to claim 1, Zarinetchi discloses an implantable medical device comprising:

- Electronics carried in the housing and configured to perform a medical therapy
- A rechargeable power source carried in the housing and coupled to the electronics (Fig 3)
- A secondary recharging coil coupled to the electronics and rechargeable power source (21)
- A magnetic shield placed on the distal side of the receiving coil to improve recharging efficiency (column 5, lines 22-26)

It is inherent that the housing has an electrical feedthrough since it has leads extending through the housing. In the alternative Zarinetchi discloses the claimed invention except for an electric feedthrough. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention as taught by Kelly, with an electrical feedthrough since it is well known in the art that implantable devices have electrical feedthroughs for providing energy.

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15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly (or Zarinetchi) et al. U.S. Patent No. 4,041,955 in view of Schulman et al. U.S. Patent No. 6,067,474.

Referring to claim 12, Kelly (or Zarinetchi) fails to disclose wherein the magnetic shield includes eddy cuts to reduce eddy current flow through the magnetic shield. However, Schulman includes eddy cuts to reduce eddy current flow through the magnetic shield (Fig. 3A-C) as a means of more accurately and efficiently improve charging.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Kelly, as taught by Schulman, to include eddy cuts to reduce eddy current flow through the magnetic shield (Fig. 3A-C) as a means of more accurately and efficiently improve charging.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly (or Zarinetchi) et al. U.S. Patent No. 4,041,955.

Kelly (or Zarinetchi) discloses the claimed invention except for wherein the device further comprises a second insulator placed between a second magnetic shield and a third magnetic shield. It would have been an obvious matter of design choice to one skilled in the art to modify the teachings of Kelly (or Zarinetchi), since the applicant has not disclosed that a second insulator placed between a second magnetic shield and a third magnetic shield provides any criticality and/or unexpected results and it appears that the invention would perform equally as well with any insulator placed between a

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second magnetic shield and a third magnetic shield, such as the insulator and shield as taught by Kelly (or Zarinetchi) as a means of protecting the shields..

19. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly (or Zarinetchi) et al. U.S. Patent No. 4,041,955.

Kelly (or Zarinetchi) discloses the claimed invention except for wherein the first and second insulator are selected from the group consisting of: plastic, mylar, and tape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Kelly (or Zarinetchi), with a first and second insulator selected from the group consisting of: plastic, mylar, and tape since it is well in the art that plastic, mylar, and tape have very good insulating properties and are used in implantable devices as insulators.

Conclusion

The Kelly et al. reference and the Zarinetchi covers the majority of the claims inherently and the Kelly et al. reference is capable of performing the functional use recitations presented in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R. B. Benfield

R.B. 12/2/02
December 2, 2002

rc
GEORGE R. EVANISKO
PRIMARY EXAMINER

12/2/2